



DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2006-25854; FMCSA-2011-0389; FMCSA-2012-0294; FMCSA-2013-0109]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to grant requests from five individuals for exemptions from the regulatory requirement that interstate commercial motor vehicle (CMV) drivers have “no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.” The regulation and the associated advisory criteria published in the Code of Federal Regulations as the “Instructions for Performing and Recording Physical Examinations” have resulted in numerous drivers being prohibited from operating CMVs in interstate commerce based on the fact that they have had one or more seizures and are taking anti-seizure medication, rather than an individual analysis of their circumstances by a qualified medical examiner. The Agency concluded that granting exemptions for these CMV drivers will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions. FMCSA grants exemptions that will allow these five individuals to operate CMVs in interstate commerce for a 2-year period. The exemptions preempt State laws and regulations and may be renewed.

DATES: The exemptions are effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The exemptions expire on [INSERT DATE 2 YEARS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Division Chief, Physical Qualifications, Office of Medical Programs, (202) 366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue, S.E., Room W64-224, Washington, DC 20590-0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

A. ELECTRONIC ACCESS

You may see all the comments online through the Federal Document Management System (FDMS) at: <http://www.regulations.gov>.

Docket: For access to the docket to read background documents or comments, go to <http://www.regulations.gov> and/or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue, S.E., Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Privacy Act: Anyone may search the electronic form of all comments received into any of DOT's dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, or other entity). You may review DOT's complete Privacy Act Statement in the Federal Register (73 FR 3316, January 17, 2008). This statement is also available at <http://Docketinfo.dot.gov>.

B. BACKGROUND

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the safety regulations for a 2-year period if it finds “such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such

exemption.” The statute also allows the Agency to renew exemptions at the end of the 2-year period.

FMCSA grants five individuals an exemption from the regulatory requirement in § 391.41(b)(8), to allow these individuals who take anti-seizure medication to operate CMVs in interstate commerce for a 2-year period. The Agency’s decision on these exemption applications is based on an individualized assessment of each applicant’s medical information, including the root cause of the respective seizure(s), the length of time elapsed since the individual’s last seizure, and each individual’s treatment regimen. In addition, the Agency reviewed each applicant’s driving record found in the Commercial Driver’s License Information System (CDLIS)¹ for commercial driver’s license (CDL) holders, and interstate and intrastate inspections recorded in Motor Carrier Management Information System (MCMIS)². For non-CDL holders, the Agency reviewed the driving records from the State licensing agency. The Agency acknowledges the potential consequences of a driver experiencing a seizure while operating a CMV. However, the Agency believes the drivers covered by the exemptions granted here have demonstrated that they are unlikely to have a seizure and their medical condition does not pose a risk to public safety.

In reaching the decision to grant these exemption requests, the Agency considered both current medical literature and information and the 2007 recommendations of the Agency’s Medical Expert Panel (MEP). The Agency previously gathered evidence for potential changes to the regulation at 49 CFR 391.41(b)(8) by conducting a comprehensive review of scientific

¹ Commercial Driver License Information System (CDLIS) is an information system that allows the exchange of commercial driver licensing information among all the States. CDLIS includes the databases of fifty-one licensing jurisdictions and the CDLIS Central Site, all connected by a telecommunications network.

² Motor Carrier Management Information System (MCMIS) is an information system that captures data from field offices through SAFETYNET, CAPRI, and other sources. It is a source for FMCSA inspection, crash, compliance review, safety audit, and registration data.

literature that was compiled into the “Evidence Report on Seizure Disorders and Commercial Vehicle Driving” (Evidence Report) [CD-ROM HD TL230.3 .E95 2007]. The Agency then convened a panel of medical experts in the field of neurology (the MEP) on May 14-15, 2007, to review 49 CFR 391.41(b)(8) and the advisory criteria regarding individuals who have experienced a seizure, and the 2007 Evidence Report. The Evidence Report and the MEP recommendations are published on-line at <http://www.fmcsa.dot.gov/rules-regulations/topics/mep/mep-reports.htm>, under Seizure Disorders, and are in the docket for this notice.

MEP Criteria for Evaluation

On October 15, 2007, the MEP issued the following recommended criteria for evaluating whether an individual with epilepsy or a seizure disorder should be allowed to operate a CMV.³ The MEP recommendations are included in previously published dockets.

Epilepsy diagnosis. If there is an epilepsy diagnosis, the applicant should be seizure-free for 8 years, on or off medication. If the individual is taking anti-seizure medication(s), the plan for medication should be stable for 2 years. Stable means no changes in medication, dosage, or frequency of medication administration. Recertification for drivers with an epilepsy diagnosis should be performed every year.

Single unprovoked seizure. If there is a single unprovoked seizure (i.e., there is no known trigger for the seizure), the individual should be seizure-free for 4 years, on or off medication. If the individual is taking anti-seizure medication(s), the plan for medication should be stable for 2 years. Stable means no changes in medication, dosage, or frequency of medication

³ Engel, J., Fisher, R.S., Krauss, G.L., Krumholz, A., and Quigg, M.S., “Expert Panel Recommendations: Seizure Disorders and Commercial Motor Vehicle Driver Safety,” FMCSA, October 15, 2007.

administration. Recertification for drivers with a single unprovoked seizure should be performed every 2 years.

Single provoked seizure. If there is a single provoked seizure (i.e., there is a known reason for the seizure), the Agency should consider specific criteria that fall into the following two categories: low-risk factors for recurrence and moderate-to-high risk factors for recurrence.

- Examples of low-risk factors for recurrence include seizures that were caused by a medication; by non-penetrating head injury with loss of consciousness less than or equal to 30 minutes; by a brief loss of consciousness not likely to recur while driving; by metabolic derangement not likely to recur; and by alcohol or illicit drug withdrawal.
- Examples of moderate-to-high-risk factors for recurrence include seizures caused by non-penetrating head injury with loss of consciousness or amnesia greater than 30 minutes, or penetrating head injury; intracerebral hemorrhage associated with a stroke or trauma; infections; intracranial hemorrhage; post-operative complications from brain surgery with significant brain hemorrhage; brain tumor; or stroke.

The MEP report indicates individuals with moderate to high-risk conditions should not be certified. Drivers with a history of a single provoked seizure with low risk factors for recurrence should be recertified every year.

Medical Review Board Recommendations and Agency Decision

FMCSA presented the MEP's findings and the Evidence Report to the Medical Review Board (MRB) for consideration. The MRB reviewed and considered the 2007 "Seizure Disorders and Commercial Driver Safety" evidence report and the 2007 MEP recommendations. The MRB recommended maintaining the current advisory criteria, which provide that "drivers with a history of epilepsy/seizures off anti-seizure medication and seizure-free for 10 years may be

qualified to drive a CMV in interstate commerce. Interstate drivers with a history of a single unprovoked seizure may be qualified to drive a CMV in interstate commerce if seizure-free and off anti-seizure medication for a 5 year period or more” [Advisory criteria to 49 CFR 391.43(f)].

The Agency acknowledges the MRB’s position on the issue but believes relevant current medical evidence supports a less conservative approach. The medical advisory criteria for epilepsy and other seizure or loss of consciousness episodes was based on the 1988 “Conference on Neurological Disorders and Commercial Drivers” (NITS Accession No. PB89-158950/AS). A copy of the report can be found in the docket referenced in this notice.

The MRB’s recommendation treats all drivers who have experienced a seizure the same, regardless of individual medical conditions and circumstances. In addition, the recommendation to continue prohibiting drivers who are taking anti-seizure medication from operating a CMV in interstate commerce does not consider a driver’s actual seizure history and time since the last seizure. The Agency has decided to use the 2007 MEP recommendations as the basis for evaluating applications for an exemption from the seizure regulation on an individual, case-by-case basis.

C. EXEMPTIONS

Following individualized assessments of the exemption applications, including a review of detailed follow-up information requested from each applicant, FMCSA is granting exemptions from 49 CFR 391.41(b)(8) to five individuals. Under current FMCSA regulations, all of the five drivers receiving exemptions from 49 CFR 391.41(b)(8) would have been considered physically qualified to drive a CMV in interstate commerce except that they presently take or have recently stopped taking anti-seizure medication. For these five drivers, the primary obstacle to medical qualification was the FMCSA Advisory Criteria for Medical Examiners, based on the 1988

“Conference on Neurological Disorders and Commercial Drivers,” stating that a driver should be off anti-seizure medication in order to drive in interstate commerce. In fact, the Advisory Criteria have little if anything to do with the actual risk of a seizure and more to do with assumptions about individuals who are taking anti-seizure medication.

In addition to evaluating the medical status of each applicant, FMCSA evaluated the crash and violation data for the five drivers, some of whom currently drive a CMV in intrastate commerce. The CDLIS and MCMIS were searched for crash and violation data on the five applicants. For non-CDL holders, the Agency reviewed the driving records from the State licensing agency.

These exemptions are contingent on the driver maintaining a stable treatment regimen and remaining seizure-free during the 2-year exemption period. The exempted drivers must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free. The driver must undergo an annual medical examination by a medical examiner, as defined by 49 CFR 390.5, following the FMCSA’s regulations for the physical qualifications for CMV drivers.

FMCSA published a notice of receipt of application and requested public comment during a 30-day public comment period in a Federal Register notice for each of the applicants. A short summary of the applicants’ qualifications and a discussion of the comments received follows this section. For applicants who were denied an exemption, a notice will be published at a later date.

D. COMMENTS

Docket # FMCSA-2006-25854

On August 9, 2007, FMCSA published a notice of receipt of exemption applications and requested public comment on nine individuals (72 FR 44916; Docket number FMCSA-2006-25854). The comment period ended on September 10, 2007. Five comments were received. A discussion of the comments were presented in a previous notice. Of the nine applicants, five were previously granted exemptions, one withdrew his request, and two were denied. The Agency has determined that the following applicant should be granted an exemption.

Jay Whitehead

Mr. Whitehead is a 51 year-old class B CDL holder in New York. He has a history of seizures and has remained seizure free since 1983. He takes anti-seizure medication with the dosage and frequency remaining the same for over 2 years. If granted the exemption, he would like to continue to drive a CMV. His physician states he is supportive of Mr. Whitehead receiving an exemption.

Docket # FMCSA-2011-0389

On January 5, 2012, FMCSA published a notice of receipt of exemption applications and requested public comment on 15 individuals (77 FR 33781; Docket number FMCSA-2011-0389). The comment period ended on February 5, 2012. Seven comments were received. A discussion of the comments were presented in a previous notice. Of the 15 applicants, three were previously granted exemptions. FMCSA has determined that the following applicant should be granted an exemption. The Agency will issue a decision on the other drivers at a later date.

Lonnie Rieker

Mr. Rieker is a 55 year-old class A CDL holder in Illinois. He has a history of a single seizure and has remained seizure free for 4 years. He takes anti-seizure medication with the dosage and frequency remaining the same for over 2 years. If granted the exemption, he would like to continue to drive a CMV. His physician states he is supportive of Mr. Rieker receiving an exemption.

Docket # FMCSA-2012-0294

On January 15, 2013, FMCSA published a notice of receipt of exemption applications and requested public comment on nine individuals (78 FR 00712; Docket number FMCSA-2012-0294). The comment period ended on February 15, 2013. Eight comments were received, including three duplicate comments. A discussion of the comments were presented in a previous notice. Of the nine applicants, eight were previously granted exemptions. FMCSA has determined that the following applicant should be granted an exemption.

Michael Ranalli

Mr. Ranalli is a 29 year-old driver in Pennsylvania. He has a history of juvenile epilepsy and has remained seizure free for 8 years. He takes anti-seizure medication with the dosage and frequency remaining the same since that time. If granted the exemption, he would like to drive a CMV. His physician states he is supportive of Mr. Ranalli receiving an exemption.

Docket # FMCSA-2013-0109

On November 13, 2013, FMCSA published a notice of receipt of exemption applications and requested public comment on 11 individuals (78 FR 68144). The comment period ended on December 13, 2013. No commenters responded to this Federal Register notice. Of the 11 applicants, four were previously granted exemptions. FMCSA has determined that the following

two applicants should be granted an exemption. The Agency will issue a decision on the other drivers at a later date.

Jeffrey Ballweg

Mr. Ballweg is 51 year-old driver in Wisconsin. He has a history of epilepsy and has remained seizure free for 8 years. He takes anti-seizure medication with the dosage and frequency remaining the same for over 2 years. If granted the exemption, he would like to drive a CMV. His physician states he is supportive of Mr. Ballweg receiving an exemption.

Bryan Couture

Mr. Couture is a 48 year-old class B CDL holder in Rhode Island. He has a history of seizure and has remained seizure free for 10 years. He takes anti-seizure medication with the dosage and frequency remaining the same for over 2 years. If granted the exemption, he would like to continue to drive a CMV. His physician states he is supportive of Mr. Couture receiving an exemption.

E. BASIS FOR EXEMPTION

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the epilepsy/seizure standard in 49 CFR 391.41(b)(8) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, the Agency's analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting the driver to driving in intrastate commerce.

Conclusion

The Agency is granting exemptions from the epilepsy standard, 49 CFR 391.41(b)(8), to five individuals based on a thorough evaluation of each driver's qualifications, safety experience, and medical condition. Safety analysis of information relating to these five applicants meets the burden of showing that granting the exemptions would achieve a level of safety that is equivalent to or greater than the level that would be achieved without the exemption. By granting the exemptions, the interstate CMV industry will gain five highly trained and experienced drivers. In accordance with 49 U.S.C. 31315(b)(1), each exemption will be valid for 2 years, with annual recertification required unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

FMCSA exempts the following five drivers for a period of 2 years with annual medical certification required: Jeffrey Ballweg (WI); Bryan Couture (RI); Michael Ranalli (PA); Lonnie Rieker (IL); and Jay Whitehead (NY) from the prohibition of CMV operations by persons with a clinical diagnosis of epilepsy or seizures. If the exemption is still in effect at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: November 21, 2014.

Larry W. Minor,
Associate Administrator for Policy.

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